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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,587	04/03/2001	Lorraine D. Butlin	IMIN.P-032	8700

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/824,587	Applicant(s) BUTLIN ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment submitted 6/20/2004 has been received. Claims 21-54 are pending. Claims 51-54 have been withdrawn.

Rejections Withdrawn

2. The rejection of claims 48-50 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the satisfaction of deposited information.
3. The rejection of claims 21-50 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment of the claims.

Claim Rejections - 35 USC § 112

4. Claims 21-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite a method for differentiating between a first state and a second state of an analyte, wherein in the first state, the analyte is present in a first set of isoforms and in the second state the analyte is present in a second set of isoforms, where the first set of isoforms differs from the second set of isoforms as a result of containing different forms of the analyte in different relative amounts.

This is understood to mean the following: A method for differentiating between a first state and a second state of an analyte, wherein the first and second state are defined as different because they contain different amount of the same isoform of the analyte.

In the arguments submitted 20 June 2004, applicant states that they are not claiming the differentiation of different isoforms. Instead, the claims are drawn to “differentiating analyte “states” which may be the result of compositions having the same isoforms in differing relative amounts.” Applicant also states that this is exactly what is shown in Example 3. Therefore, the above interpretation of the amended claim is consistent with the arguments submitted.

However, the specification fails to teach such a method. The specification, indeed teach a method for performing a sequential and a “substantial simultaneous” assay on the same sample, or contemporaneous samples, however, the specification does not teach that the results obtained from these two assays differentiate between a first state and a second state of an analyte. Example 3 teaches the detection of FSH concentration in 8 consecutive daily urine samples from one fertile woman and 9 consecutive daily urine samples from one post-menopausal woman. FSH concentration in each sample is measured using the sequential and simultaneous assays. The results shown are indicative of different amounts of FSH in a pre-menopausal sample versus a post-menopausal sample, i.e. the ratio taken in one set of sample (or more accurately, in one pre-menopausal woman) is compared to the ratio taken in another set of sample (or more accurately, in one post-menopausal woman) and a differentiation between a pre and post menopausal condition is made. The results do not show that in one set of sample, for example, D14, a first state and a second state of FSH (i.e. different isoforms of FSH) is differentiated, such as claimed. Throughout the specification and specifically at pages 1-2, the different states of analytes are defined as a plurality of forms such as isoforms (forms differ from one another in either physical characteristics, e.g. separable by charge) or chemical characteristics (e.g. glycoforms in the case of FSH or similar molecules), or both. The specification also states that differences in the chemical properties the glycoprotein side chains

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may influence the physical properties (e.g. charge) of the overall molecule, such that different glycoforms may also constitute different isoforms. Specifically, in FSH for example, the alpha and beta peptide chains are the same in all FSH forms, but subtle differences occur in the glycoprotein side chains. Therefore, the relative proportions of the forms of FSH existing in the menopause state are different from those the pre-menopause state.

Nowhere in the specification is there a description of a method for differentiating between two different states of an analyte where the different states are defined as compositions having the same isoforms in differing relative amounts in contemporaneous samples or aliquots of a single sample. Furthermore, nothing in the specification teaches one how to distinguish between the different isoforms (as defined on pages 1, 2 and 8 of the specification) of the analyte based on their amount in a set of sample; nor is there a teaching that the different isoforms of the analyte can be differentiated using the method of the invention.

5. Claims 21-50 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for distinguishing between pre-menopausal and post-menopausal FSH in samples at different time intervals, does not reasonably provide enablement for a method for differentiating between a first state and a second state of an analyte in contemporaneous samples using the same reagents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification page 9, lines 6-10 teaches the analysis of FSH samples using a pair of novel anti-FSH monoclonal antibodies that distinguish between pre-menopausal and post-menopausal FSH samples. The specification further teaches that for more accurate diagnosis of

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menopausal conditions the assay results should be determined numerically, and expressed as a ratio of the signals of the first and second assays. A significant change in this ratio can indicate transition from a pre-menopausal to a post-menopausal state, or vice-versa. Thus the results from a series of contemporaneous tests performed, for example, every few weeks, can be collated and any change in the observed signal ratio used to diagnose a change in condition.

Page 11, lines 5-19.

The specification does not teach the method as claim in claim 21, mainly the performance of a one-step and two-step assays on contemporaneous samples from the same source, and the comparison of the amount of analyte detected in the one-step assay and the two-step assay, where the amount of analyte found in these assays is used to differentiate between two different states of the analyte.

Response to Arguments

6. Applicant's arguments filed 20 June 2004 have been fully considered but they are not persuasive.

All of applicant's arguments have been addressed above with respect to the 112, first paragraph rejection. Specifically, the specification does not provide adequate written description for the claims as amended.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
9/3/04